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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request:

Post-Award Reporting Requirements Including New Research Performance Progress

Report Collection; Revision

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

This proposed information collection was previously published in the **Federal Register** on March 5, 2012, page 13131 (corrected on March 26, 2012, page 17488), and allowed 60 days for public comment. One public comment was received, which asked for clarification about new reporting burdens. It was noted in follow-up that NIH has seen a 21-percent increase in competing applications since the last clearance, which has resulted in an increase in the burden hours. We are also transitioning to the Research Performance Progress Report as mandated by OMB. The purpose of this notice is to allow an additional 30 days for public comment.

PROPOSED COLLECTION: *Title:* Public Health Service (PHS) Post-award Reporting Requirements. *Type of Information Collection Request:* Revision, OMB 0925-0002, Expiration Date 06/30/2012. This collection represents a consolidation of post-award reporting requirements under the Paperwork Reduction Act and includes the new Research Performance Progress Report (RPPR). It also includes continued use of the PHS Non-competing Continuation

Progress Report (PHS 2590, currently approved under 0925–0001, expiration 06/30/2012), and the NIH AHRQ Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Progress Report for Continuation Support (PHS 416–9). Only one interim progress report (RPPR or PHS2590/416–9) will be utilized for any given award until the RPPR is fully implemented for all awards. This collection also includes other PHS post-award reporting requirements: PHS 416–7 NRSA Termination Notice and PHS 6031-1 NRSA Annual Payback Activities Certification. Post-award reporting requirements previously cleared under OMB 0925-0001 now included under 0925-0002 are: PHS 2271 Statement of Appointment, HHS 568 Final Invention Statement and Certification, Final Progress Report instructions, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. Pre-award reporting requirements are simultaneously consolidated under 0925–0001.

Need and Use of Information Collection: The RPPR will replace existing interim performance reports used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR requires the maintenance of dual reporting processes for a period of time. Thus this information collection is for the new use of the RPPR, the continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), and the use of the NIH AHRQ Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Progress Report for Continuation Support (PHS 416–9). Only one interim progress report (RPPR or PHS2590/416–9) will be utilized for any given award. The PHS 416–7, 2271, and 6031–1 are used by NRSA recipients to activate, terminate, and provide

for payback of an NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another.

Frequency of response: Grantees are required to report annually. *Affected Public:* Universities and other research institutions; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* University administrators and principal investigators. The annual reporting burden is as follows: *Total Estimated Number of Respondents:* 112,986. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 5.6. *Estimated Total Annual Burden Hours Requested:* 640,677. The annualized cost to respondents is estimated to be \$22,423,709.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov; or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Seleda M. Perryman, Chief, Project Clearance Officer, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3509, 6705 Rockledge Drive, Bethesda, MD 20892-7974; or call non-toll-free number 301-594-7949; or e-mail your request, including your address to: perrymansm@od.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Date: 6/25/12

Lawrence A. Tabak,
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National Institutes of Health

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